Supporting Statement – Part A
Dispute Resolution for Discarded Drug Refunds
(CMS-10835, OMB 0938-1435)

BACKGROUND

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) (hereinafter is referred to as "the Infrastructure Act") amended section 1847A of the Social Security Act (hereinafter is referred to as "the Act") to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is the amount of discarded drug or biological (hereafter, drug) that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter. A refundable single-dose container or single-use package drug does not include a radiopharmaceutical or imaging agent, certain drugs requiring filtration, and certain new drugs. There are two aspects to implementation of this provision (one finalized in the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) final rule and one proposed in the CY 2024 PFS notice of proposed rulemaking (NPRM)) that require collection of information.

First, in the CY 2023 PFS final rule, we finalized at §414.940 the implementation of section 90004 of the Infrastructure Act including a dispute resolution process, which requires collection of information. We finalized that the dispute must include the following information on an error report: (1) Manufacturer name and address; (2) The name, telephone number, and email address of one or more employees or representatives of the manufacturer with whom the Secretary may discuss the claimed errors; (3) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation; and (4) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of how the manufacturer established that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

Second, we propose an application process through which manufacturers can request increased applicable percentage for a drug in the CY 2024 PFS NRPM. Paragraph (3)(B)(ii) of the new section provides that, in the case of a refundable single-dose container or single-use package drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary may, through notice and comment rulemaking, increase the applicable percentage otherwise applicable as determined appropriate by the Secretary. In the CY 2024 PFS NPRM, we are proposing modifications to §414.940 to establish an application process so manufacturers may request that CMS consider whether an increased applicable percentage would be appropriate for a particular drug in light of its unique circumstances.

In the CY 2024 NPRM, we propose that, to request we consider increasing the applicable percentage for a particular refundable drug, a manufacturer must submit the following: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling for the drug; (3) justification for the

consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested increase in the applicable percentage.

A. JUSTIFICATION

1 . Need and Legal Basis

As a part of implementing section 90004 of the Infrastructure Act, we recognize the need for establishing a dispute resolution process because of the nature of determining the estimated total allowed charges for a given calendar quarter and the methods by which the estimated refund amount is determined. Although a dispute resolution process is not expressly required by section 1847A(h) of the Act, we believe that proactively establishing such a process will aid in the successful implementation of this provision. We finalized in the CY 2023 PFS that each manufacturer has an opportunity to dispute the report by submitting an error report as described in this section.

In addition, we recognize that there are products subject to the discarded drug refund provision that may indeed have a unique circumstance, and an increased applicable percentage for these products would have to be determined through future notice and comment rulemaking as required by the statutory provision. Although we finalized an increased applicable percentage for one drug with unique circumstances in the CY 2023 final rule and we are proposing an increased applicable percentage for two categories of drugs with unique circumstances in the CY 2024 proposed rule, we believe a formal application process would provide drug manufacturers a transparent avenue to provide CMS with information that could justify that a drug has a unique circumstance and should have an increased applicable percentage. The proposed application process would be advantageous to manufacturers by providing a clear process in regulation by which an increased applicable percentage can be requested, particularly because of the statutory requirement that these determinations be made through notice and comment rulemaking.

2. Information Users

Error Report: Manufacturers of drugs for which refunds are owed may submit an error report to CMS. This error report will contain information as described in the background section above. CMS will use this information to evaluate the refund amount and make any corrections or adjustments to the refund amount if CMS finds there was indeed an error. We will evaluate error reports and will decide whether the information (such as number of discarded billing units or refund amount calculation) requires correction based on the information provided. In the CY 2023 final rule, we finalized that if we find that a different refund amount is owed than what was stated on the report, we will issue a new report with updated discarded amounts and/or refund. We finalized that if we disagree with the dispute, we will notify the manufacturer that refund amount on the report is still owed and should be paid.

Application process for increased applicable percentage: In the CY 2024 PFS NPRM, we are proposing that manufacturers of drugs or biologicals may apply for an increased applicable percentage (based on unique circumstances) on an annual basis, which is proposed to be submitted to CMS by February 1 of the calendar year prior to the year the increased applicable

percentage would apply (for example, applications for increased applicable percentages effective January 1, 2025 would be due to CMS by February 1, 2024). We propose to discuss our analyses of applications in the PFS rulemaking immediately following the application period, and to communicate in the proposed rule whether we consider the drug to have unique circumstances that warrant an increased applicable percentage. We would also include proposals, if any, for increased applicable percentages, along with a summary of any applications for which we determined not to propose an increase in the applicable percentage.

3. Use of Information Technology

The collection of information for neither the error report nor the unique circumstance application involves use of automated, electronic, mechanical, or other technological collection techniques. An electronic collection system of such information is not currently available. We would require a signature from respondents and if CMS had the capability of accepting electronic signatures, we could consider that the error report be submitted electronically.

Since both the error report and the proposed application process for increased applicable percentage contain very specific information, regarding the refund amount owed and the amount of discarded drug for the error report, and regarding the FDA-approved label, drug properties, and/or minimum fill amount for the unique circumstance application, there is very little opportunity for automation. We anticipate a very small number of error reports (10 or less per year) and increased applicable percentage applications (30 or less per year), therefore, it would not be cost effective to develop novel collection systems.

4. Duplication of Efforts

These information collections do not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

Manufacturers of drugs and biologicals are generally not considered small businesses. Therefore, the collection of error reports does not impact small businesses.

6. Less Frequent Collection

Error report: We finalized in the CY 2023 PFS final rule that reports described in section 1847A(h) of the Act be sent from CMS to manufacturers of refundable single-dose container or single-use package drug once annually. Therefore, the submission of error reports from manufacturers to CMS is to be done once annually. We would not be able to decrease the frequency of the collection of error reports to adequately address disputes in a timely manner. Less frequent error reports could have negative impacts on implementation such as delaying payment of refunds. We considered a quarterly process for implementation of this provision, but thought it less burdensome for CMS resources and for manufacturers to propose implementation of an annual process (including the collection of error reports).

Application process for increased applicable percentage: In the CY 2024 NPRM, we are proposing to establish a process through which drug manufacturers will have the opportunity to submit a unique circumstance application once annually. Since we are implementing all aspects of section 1847A(h) of the Act through notice-and-comment rulemaking (generally, on an annual basis through the PFS CY rule), we cannot have a more frequent application process. As we anticipate new drugs subject to the discarded drug refund provision to be marketed each year, and that some manufacturers will make changes to their packaging to reduce liabilities under the provision, a process with application periods less frequent than once a year would pose a disadvantage to manufacturers.

7. Special Circumstances

Neither the finalized collection of error reports nor the proposed the application process for increased applicable percentage has any special circumstances.

8. Federal Register/Outside Consultation

Serving as the 60-day notice for the proposal for the application process for increased applicable percentage, the CY 2024 PFS proposed rule (CMS-1784-P; RIN 0938-AV07) filed for public inspection on July 13, 2023 at the Office of the Federal Register and published in the Federal Register on August 7, 2023 (88 FR 52262). Comments must be received by 5 p.m. on September 11, 2023.

9. Payments/Gifts to Respondents

Respondents will not receive any payments or gifts as a condition of complying with this information collection request. Although the respondents will not receive payments or gifts, the end result of the dispute or application for an increased applicable percentage may result in a change to the refund amount owed by the respondent.

10. Confidentiality

We are not providing any assurance of confidentiality to the respondents.

11. Sensitive Questions

There is no collection of information that is of a sensitive nature.

12. Burden Estimates (Hours & Wages)

Consistent with the estimated annual burden per respondent/recordkeeper for similar error reports utilized to implement the Branded Prescription Drug Fee (76 FR 51310), we estimate the annual burden per respondent/recordkeeper to be 40 hours. If we anticipate no more than 10 disputes per year, the total annual reporting and/or recordkeeping burden would be 400 hours (10 error reports per year x 40 hr per respondent). Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2022) for Category 43-6014 (Secretaries

and Administrative Assistants), the mean hourly wage for an administrative assistant is $20.87.[1] We have added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $41.74 ($20.87 + $20.87). Therefore, we estimate an annual cost of this burden to be $16,696 ($41.74/hr x 400 hr).

Separately, we estimate that the burden per respondent/applicant of drafting and submitting the unique circumstance application to be 5 hours. We anticipate 25 applications in the initial year that applications are available, and a total burden related to drafting and submission of 125 hours (25 applications x 5 hr per respondent/applicant). Once a manufacturer has applied for a drug and a decision has been made regarding whether an increased applicable percentage is appropriate, the manufacturer would not need to apply again. Therefore, subsequent years we would expect a smaller number of applications. When evaluating the approval dates of these 25 drugs, we find that there is a range of 0 to 4 drugs per year approved that would be expected to owe a refund of more than $50,000 per year. From 2010—2020, the mean number of such approvals is 1.45 per year. If rounded up, we estimate that we would typically receive 2 applications per year except the initial application year.

Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2022) for Category 43-6014 (Secretaries and Administrative Assistants), the mean hourly wage for an administrative assistant is $20.87.[2] We have added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $41.74 ($20.87 + $20.87). Therefore, we estimate a cost of this burden to be $5,218 ($41.74/hr x 125 hr) in the initial year. For subsequent years, we estimate a total annual burden related to drafting and submission of 10 hours (2 applications x 5 hr per respondent/applicant) at an annual cost of $418 (41.74/hr x 10 hr).

OMB control number	CFR Section	Respondents	Responses Per Respondent	Burden per Response (hours)	Total Annual Burden	Labor Cost (dollars/hour)	Total Cost
0938-1435	414.940	10	1	40	400	$41.74	$16,696
0938-1435	414.940	25 in the initial year; 2 in subsequent years	1	5	125 in the initial year; 10 in subsequent years	$41.74	$5,218 in the initial year; $418 in subsequent years

13. Capital Costs

There are no additional recordkeeping or capital costs.

[1] https://www.bls.gov/oes/current/oes436014.htm
[2] https://www.bls.gov/oes/current/oes436014.htm

14. Cost to Federal Government

The calculations for employees' hourly salary were obtained from the OPM website, with an additional 100% to account for fringe benefits.

Task	**Estimated Annual Cost**
3 GS-13:2 x $102.71 x 40 hours	$12,325.20
2 GS-14:2 x $121.38 x 40 hours	$9,710.40
3 GS-15:3 x $142.77 x 8 hours	$3,426.48
Total Costs to Government	**$25,462.08**

15. Changes to Burden

In the CY 2023 PFS final rule, we finalized a dispute resolution process, through which each manufacturer can assert to CMS there are errors in its report. Under this process, upon finding what the manufacturer believes to be an error, the manufacturer may submit to CMS an identification of the error along with a proposed recalculation if the error is mathematical, or an explanation of the error and proposed correction to the error if it is of a nature other than mathematical. The burden imposed on respondents consists of the analysis of the report, drafting of an error report, and submission of the error report.

In the CY 2024 PFS proposed rule, we are proposing an application process through which each manufacturer can request that we consider increasing the applicable percentage for a particular drug based on unique circumstances. Under this process, by February 1 of the calendar year prior to the year the increased applicable percentage would apply, manufacturers would submit to CMS: (1) a written request that a drug be considered for an increased applicable percentage based on its unique circumstances; (2) FDA-approved labeling; (3) justification for the consideration of an increased applicable percentage based on such unique circumstances; and (4) justification for the requested applicable percentage. The burden imposed on respondents consists of the drafting and submission of the request for unique circumstance consideration.

16. Publication/Tabulation Dates

The data collected will not be made public.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

The proposed collection does not involve any exceptions to the certification statement identified in line 19 of OMB Form 83-I.